



PATENT APPLICATION
DOCKET NO. CLANACR_001NP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: PACIORETTY ET AL.

SERIAL NO:

10699195
10/669,195

FILED:

10/31/2003

TITLE:

COMPOSITIONS AND METHODS
FOR THE TREATMENT OF HIV-
ASSOCIATED FAT
MALDISTRIBUTION AND
HYPERTRIGLYCERIDEMIA

ART UNIT:

1617

EXAMINER:

CHONG, YONG SOO

DOCKET NO:

CLANACR_001NP

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Dear Sir:

This communication is in response to the Examiner's Action dated 01/16/07.

Claims 1 - 40 are pending in this application.

ELECTION OF RESTRICTION REQUIREMENT

The Examiner has required that the claimed invention be restricted under 35 U.S.C. §121, to:

- I. Claims 1 (in part), 2-6, 8-9, 12 (in part), 13-17, 19-20 are drawn to a composition comprising a conjugated fatty acid and a thiol-containing compound, classified in 436/86.
- II. Claims 1 (in part), 2-6, 10-11 are drawn to a composition comprising a conjugated fatty acid and a bioavailable form of trivalent chromium, classified in 514/557.
- III. Claims 1 (in part), 7-9, 12 (in part), 18-20 are drawn to a composition comprising a conjugated fatty alcohol and a thiol-containing compound, classified in 514/724.
- IV. Claims 1 (in part), 7, 10-11 are drawn to a composition comprising a conjugated fatty alcohol and a bioavailable form of trivalent chromium, classified in 424/655.
- V. Claims 21 (in part), 22-26, 28-29, 32 (in part), 33-37, 39-40 are drawn to a method of treating, preventing, or normalizing fat maldistribution resulting from anti-retroviral treatment of HIV-1 infection in a subject by administering a composition comprising a conjugated fatty acid and a thiol-containing compound, classified in 436/86.
- VI. Claims 21 (in part), 22-26, 30-31 are drawn to a method of treating, preventing, or normalizing fat maldistribution resulting from anti-retroviral treatment of HIV-1 infection in a subject by administering a composition

comprising a conjugated fatty acid and a bioavailable form of trivalent chromium, classified in 514/557.

VII. Claims 21 (in part), 27-29, 32 (in part), 38-40 are drawn to a method of treating, preventing, or normalizing fat maldistribution resulting from anti-retroviral treatment of HIV-1 infection in a subject by administering a composition comprising a conjugated fatty alcohol and a thiol-containing compound, classified in 514/724.

VIII. Claims 21 (in part), 27, 30-31 are drawn to a method of treating, preventing, or normalizing fat maldistribution resulting from anti-retroviral treatment of HIA-1 infection in a subject by administering a composition comprising a conjugated fatty alcohol and a bioavailable form of trivalent chromium, classified in 424/655.

The Examiner has stated that these groups are distinct because:

Inventions I-IV and V-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, there are many supplements that comprise conjugated fatty acids, such as linoleic acid found in fish oil for a variety of benefits for the human diet including anticancer benefits. Such dietary supplements can also contain various thiol-containing compounds such as lipoic acid because of its antioxidant activity.

Inventions I-IV and V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions, conjugated fatty acids, conjugated fatty alcohols, thiol-containing compounds, and bioavailable forms of trivalent chromium are totally different compounds. They have different structures, thus leading to different reactivity, binding affinity, mechanism, stability, polarity, bioavailability, efficacy, and modes of action. Furthermore, the search for one will not lead to information regarding another, and vice

versa. Because these inventions are distinct for the reasons given above and the search required for one invention is not required for another, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to more than one species of the generic invention.

The species are as follows:

- 1) a single disclosed conjugated fatty acid, for example triglyceride of conjugated linoleic acid
- 2) a single disclosed conjugated fatty alcohol, for example conjugated linoleic alcohol.

If applicant elects Invention I-II, V-VI, applicant is further required to elect a single disclosed fatty acid from subsection 1. Currently, claims 2-6, 13-17, 22-26, 33-37 are generic to a plurality of disclosed patentably distinct species.

If applicant elects Inventions III-IV, VII-VIII, applicant is further required to elect a single disclosed conjugated fatty alcohol from subsection 2. Currently, claims 7, 18, 27, 38 are generic to a plurality of disclosed patentably distinct species.

Applicants hereby request reconsideration and elect, with traverse, the subject matter of Group V drawn to a method of treating, preventing, or normalizing fat maldistribution resulting from anti-retroviral treatment of HIV-1 infection in a subject by administering a composition comprising a conjugated fatty acid and a thiol-containing compound. Further, the applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2-6, 13-17, 22-26, 33-

37 are generic to a plurality of disclosed patentably distinct species. Applicants further elect the triglyceride of conjugated linoleic acid.

However, reconsideration of the restriction requirement is requested on the grounds that the invention is a unitary invention. The Examiner alleges Inventions I-IV and V-VIII are related as product and processes of use. As example the Examiner states, "In the instant case, there are many supplements that comprise conjugated fatty acids, such as linoleic acid found in fish oil for a variety of benefits for the human diet including anticancer benefits. Such dietary supplements can also contain various thiol-containing compounds such as lipoic acid because of its antioxidant activity." The applicants respectfully disagree because the ability of thiol compounds to reduce free radicals is associated with the formation of thiyl radicals and the rate and efficiency of removal of thiyl radicals has a critical effect on antioxidant or prooxidant actions of thiols. Indeed, lipoic acid has been described in many studies to have both prooxidant as well as antioxidant activity (Cakatay, U., Kayali, R., Sivas, A., and Tekeli, F. (2005) Prooxidant activities of alpha-lipoic acid on oxidative protein damage in the aging rat heart muscle. *Arch Gerontol Geriatr* 40, 231-40). Thus, the product as claimed could not prudently be used in this materially different process.

The Examiner further asserts, "Inventions I-IV and V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects." Applicants deferentially maintain that the instant application discloses the use of conjugated fatty acids, thiol-containing compounds, and bioavailable forms of trivalent chromium together. Examiner states, "In the instant case, the different inventions,

conjugated fatty acids, conjugated fatty alcohols, thiol-containing compounds, and bioavailable forms of trivalent chromium are totally different compounds. They have different structures, thus leading to different reactivity, binding affinity, mechanism, stability, polarity, bioavailability, efficacy, and modes of action. Furthermore, the search for one will not lead to information regarding another, and vice versa." Applicants appreciate that conjugated fatty acids, conjugated fatty alcohols, thiol-containing compounds, and bioavailable forms of trivalent chromium are totally different compounds and as such have the characteristics described by the Examiner. However, Applicants believe that these differences form the basis for novelty of both product and process and that it would not create an undue burden for the Examiner to examine these groups concurrently. Therefore, the Applicants respectfully request reconsideration in this matter and withdrawal of this requirement.

Dated this 7TH day of February, 2007

Respectfully submitted,

BIONEXUS



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